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10/526,079	02/17/2006	David A Sack	29731-214498	8323

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EXAMINER	
TONGUE, LAKIA J	

ART UNIT	PAPER NUMBER
1645	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/526,079	SACK ET AL.	
	Examiner	Art Unit	
	LAKIA J. TONGUE	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 August 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *5 and 6* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4 and 7-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 February 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/28/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Matlab I, which read on claims 1-4 and 7-20, in the reply filed on August 4, 2008 is acknowledged.

Applicant argues that:

1) No notice of lack of unity was received in PCT application US2003/026968, on which the present U.S. national stage filing is based, and that therefore all of the claims should be considered to encompass a single inventive concept.

2) It is submitted that Matlab I, Matlab II and Matlab III are all strains of *Vibrio cholerae*, and that searching all of the strains would not pose an undue burden on the Examiner.

Applicant's arguments have been fully considered but are deemed non persuasive.

With Regard to Point 1, on the international level, all written opinions are nonbinding and a patent does not issue; what does issue is an international preliminary examination report (IPER), which is nonbinding on the Elected States. See M.P.E.P. § 1878.01, Item V.

With regard to Point 2, the inventions above are patentably distinct. A reference that would anticipate one strain would not necessarily anticipate or even make obvious another strain. The search for each of the above inventions would not be co-extensive in scope particularly with regard to the literature search. Further, burden consists not only of specific searching of classes and subclasses, but also of searching multiple

databases for foreign references and literature searches. Burden also resides in the examination of independent claim sets for clarity, enablement, and double patenting issues. Finally, the consideration for patentability is different in each case. Thus, it would be an undue burden to examine all of the above inventions in one application and the restriction for examination purposes as indicated above is deemed proper.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-20 are pending. Claims 21-47 have been canceled. Claims 5 and 6 have been withdrawn from further consideration as being drawn to non-elected inventions. Claims 1-4 and 7-20 are currently under examination.

Information Disclosure Statement

2. The information disclosure statement filed February 28, 2005 fails to comply with 37 CFR 1.98(a)(1), which requires the following: (1) a list of all patents, publications, applications, or other information submitted for consideration by the Office; (2) U.S. patents and U.S. patent application publications listed in a section separately from citations of other documents; (3) the application number of the application in which the information disclosure statement is being submitted on each page of the list; (4) a column that provides a blank space next to each document to be considered, for the examiner's initials; and (5) a heading that clearly indicates that the list is an information disclosure statement. The information disclosure statement has been placed in the application file, but the information referred to therein has not been considered.

Moreover, the listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Claim Objections

3. Claims 1 and 7-9 are objected to because of the following informalities: The claims recite language drawn to non-elected inventions. Appropriate correction is required.

4. Claim 9 is objected to because it is not clear which strain corresponds to which designation. The Examiner is suggesting that Applicant amend claim 9 to add "respectively" before the period.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 9-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains

subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) states, "The amount of guidance or direction needed to enable the invention is inversely related to the amount of knowledge in the state of the art as well as the predictability in the art." "The "amount of guidance or direction" refers to that information in the application, as originally filed, that teaches exactly how to make or use the invention. The more that is known in the prior art about the nature of the invention, how to make, and how to use the invention, and the more predictable the art is, the less information needs to be explicitly stated in the specification. In contrast, if little is known in the prior art about the nature of the invention and the art is unpredictable, the specification would need more detail as to how to make and use the invention in order to be enabling" (MPEP 2164.03). The MPEP further states that physiological activity can be considered inherently unpredictable. Thus, Applicant assumes a certain burden in establishing that inventions involving physiological activity are enabled.

Factors to be considered in determining whether a disclosure would require undue experimentation have been reiterated by the Court of Appeals in In re Wands, 8 USPQ2d 1400 at 1404 (CRFC1988). The Wands factors have been considered in the establishment of this scope of enablement rejection. These factors include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the

invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and (8) the breadth of the claims.

All of the Wands factors have been considered with regard to the instant claims, with the most relevant factors discussed below.

Nature of the invention: The rejected claims are drawn to a vaccine for protection against cholera comprising *V. cholerae* having the any identifying characteristics in common with *Vibrio cholerae* strain Matlab.

Breadth of the claims: The claims are broadly drawn and encompass a vaccine which comprises: any strain of *V. cholerae* having any of the identifying characteristics of *V. cholerae* strain Matlab I for protection against cholera and other maladies.

Direction or guidance presented in the specification: The specification does not provide substantive evidence that the claimed vaccine is capable of preventing cholera. A vaccine must by definition provide an immunoprotective response upon administration. The specification does not provide substantive evidence that the claimed vaccine is capable of inducing protective immunity against cholera. This demonstration is required for the skilled artisan to be able to use the claimed composition for their intended purpose of preventing cholera. Without this demonstration, the skilled artisan would not be able to reasonably predict the outcome of the administration of the claimed vaccine, i.e. would not be able to accurately predict if protective immunity has been induced. The instant specification discloses the construction of non-toxigenic strains as well as the examination of phenotypic and genotypic traits. The specification does not

disclose an example where a pathogen free subject was administered the claimed vaccine and as a result the subject was protected from Cholera or any other malady. The specification is silent with regard to whether or not the above-mentioned vaccine was ever administered to a subject that was not infected with cholera prior to the administration of the claimed vaccine. The specification is silent with regard to any data showing protection. The specification is also remiss in setting forth what specific "characteristics" must be possessed by a given *Vibrio cholerae* strain to have efficacy as a vaccine against a given malady.

CDC (http://wonder.cdc.gov/wonder/prevguid/p0000002/p0000002.asp, accessed on September 19, 2008) discloses that while there is a vaccine available for cholera, it confers only brief and incomplete immunity and is not recommended for travelers (see page 3 of 4; Is a vaccine available to prevent cholera?). Moreover, CDC discloses that travelers to areas where cholera has occurred should: drink only water that you have boiled or treated with chlorine or iodine, eat only foods that have been thoroughly cooked and are still hot, or fruit that you have peeled yourself, avoid undercooked or raw fish or shellfish, make sure all vegetables are cooked -- avoid salads, avoid foods and beverages from street vendors and do not bring perishable seafood back to the United States (see page 2 of 4; What should travelers do to avoid getting cholera?).

Additionally, the claims are drawn to a vaccine for protection against cholera comprising *V. cholerae* having the any identifying characteristics in common with *Vibrio cholerae* strain Matlab. The specification is silent with regard to which specific immunoepitopes are capable of inducing a protective response against cholera.

Moreover, as evidenced by Greenspan et al. (Nature Biotechnology 17: 936-937, 1999), defining epitopes is not as easy as it seems. Greenspan et al. recommends defining an epitope by the structural characterization of the molecular interface between the antigen and the antibody is necessary to define an "epitope" (page 937, column 2). According to Greenspan et al., an epitope will include residues that make contacts with a ligand, here the antibody, but are energetically neutral, or even destabilizing to binding. Furthermore, an epitope will not include any residue not contacted by the antibody, even though substitution of such a residue might profoundly affect binding. Accordingly, it follows the epitope to which any given antibody binds can only be identified empirically. Even using a competition assay, the skilled artisan cannot determine whether an antibody binds the same epitope as another antibody because an antibody that competes with another does not necessarily bind the same epitope as the other; rather, one antibody may bind a spatially overlapping epitope to sterically hinder binding of the other. Therefore, absent a detailed and particular description of a representative number, or at least a substantial number of the members of the genus of epitopes to which the members of the claimed genus of antibodies must bind, the skilled artisan could not immediately recognize or distinguish members of the claimed genus of antibodies.

Presence or absence of working examples: There are no working examples, which suggest a vaccine for protection against cholera comprising *V. cholerae* having the identifying characteristics of *V. cholerae* selected from the group consisting of Matlab I, Matlab II and Matlab III.

Quantity of experimentation necessary: The quantity of experimentation necessary would be undue. Reasonable correlation must exist between the scope of the claims and scope of enablement set forth, and it cannot be predicted from the disclosure how to make/use the claimed genus. In view of the above, one of skill in the art would be forced into undue experimentation to practice the claimed invention.

Thus, for all these reasons, the specification is not considered to be enabling for one skilled in the art to make and use the claimed invention as the amount of experimentation required is undue, due to the broad scope of the claims, the lack of guidance and working examples provided in the specification and the high degree of unpredictability as evidence by the state of the prior art, attempting the construct and test variants of the claimed invention would constitute undue experimentation.

6. Claims 9-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The rejected claims are drawn to a vaccine for protection against cholera comprising *V. cholerae* having the any identifying characteristics in common with *Vibrio cholerae* strain Matlab.

To fulfill the written description requirements set forth under 35 USC § 112, first paragraph, the specification must describe at least a substantial number of the

members of the claimed genus of antigens or alternatively describe a representative member of the claimed genus, which shares a particularly defining feature common to at least a substantial number of the members of the claimed genus, which would enable the skilled artisan to immediately recognize and distinguish its members from others, so as to reasonably convey to the skilled artisan that Applicant has possession of the claimed invention.

A representative number of species means that the species which are adequately described are representative of the entire genus. The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, disclosure of drawings, or by disclosure of relevant identifying characteristics, for example, structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus.

The specification does not provide substantive evidence that the claimed vaccine is capable of preventing cholera. A vaccine must by definition provide an immunoprotective response upon administration. The specification does not provide substantive evidence that the claimed vaccine is capable of inducing protective immunity against cholera. This demonstration is required for the skilled artisan to be able to use the claimed composition for their intended purpose of preventing cholera. Without this demonstration, the skilled artisan would not be able to reasonably predict

the outcome of the administration of the claimed vaccine, i.e. would not be able to accurately predict if protective immunity has been induced. The instant specification discloses the construction of non-toxigenic strains as well as the examination of phenotypic and genotypic traits. The specification does not disclose an example where a pathogen free subject was administered the claimed vaccine and as a result the subject was protected from Cholera or any other malady. The specification is silent with regard to whether or not the above-mentioned vaccine was ever administered to a subject that was not infected with cholera prior to the administration of the claimed vaccine. The specification is silent with regard to any data showing protection. The specification is also remiss in setting forth what specific "characteristics" must be possessed by a given *Vibrio cholerae* strain to have efficacy as a vaccine against a given malady.

CDC (http://wonder.cdc.gov/wonder/prevguid/p0000002/p0000002.asp, accessed on September 19, 2008) discloses that while there is a vaccine available for cholera, it confers only brief and incomplete immunity and is not recommended for travelers (see page 3 of 4; Is a vaccine available to prevent cholera?). Moreover, CDC discloses that travelers to areas where cholera has occurred should: drink only water that you have boiled or treated with chlorine or iodine, eat only foods that have been thoroughly cooked and are still hot, or fruit that you have peeled yourself, avoid undercooked or raw fish or shellfish, make sure all vegetables are cooked -- avoid salads, avoid foods and beverages from street vendors and do not bring perishable seafood back to the United States (see page 2 of 4; What should travelers do to avoid getting cholera?).

Additionally, the claims are drawn to a vaccine for protection against cholera comprising *V. cholerae* having the any identifying characteristics in common with *Vibrio cholerae* strain Matlab. The specification is silent with regard to which specific immunoepitopes are capable of inducing a protective response against cholera.

Moreover, as evidenced by Greenspan et al. (Nature Biotechnology 17: 936-937, 1999), defining epitopes is not as easy as it seems. Greenspan et al. recommends defining an epitope by the structural characterization of the molecular interface between the antigen and the antibody is necessary to define an "epitope" (page 937, column 2). According to Greenspan et al., an epitope will include residues that make contacts with a ligand, here the antibody, but are energetically neutral, or even destabilizing to binding. Furthermore, an epitope will not include any residue not contacted by the antibody, even though substitution of such a residue might profoundly affect binding. Accordingly, it follows the epitope to which any given antibody binds can only be identified empirically. Even using a competition assay, the skilled artisan cannot determine whether an antibody binds the same epitope as another antibody because an antibody that competes with another does not necessarily bind the same epitope as the other; rather, one antibody may bind a spatially overlapping epitope to sterically hinder binding of the other. Therefore, absent a detailed and particular description of a representative number, or at least a substantial number of the members of the genus of epitopes to which the members of the claimed genus of antibodies must bind, the skilled artisan could not immediately recognize or distinguish members of the claimed genus of antibodies.

Adequate written description requires more than a mere statement that it is part of the invention. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

The University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404. 1405 held that: ...To fulfill the written description requirement, a patent specification must describe an invention and does so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines Inc. , 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli , 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2datl966.

Further, Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page

1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116). The skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polypeptides, and therefore, conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. *See Fiers v. Revel, 25 USPQ2d 1601 at 1606 (CAFC 1993).*

Therefore, for all these reasons the specification lacks adequate written description, and one of skill in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-4 and 7-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-4 and 7-9 are rendered vague and indefinite by the use of the terms "identifying characteristics". It is unclear what is meant by said terms, as it is not explicitly defined in the specification. What constitutes "identifying characteristics"? What identifying characteristics must be maintained to produce protection? As written, it is impossible to determine the metes and bounds of the claimed invention.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-4, 8-13 and 15-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Clemens et al. (American Journal of Epidemiology, 1995; 142(7): 759-64).

The rejected claims are drawn to an isolated strain of *V. cholerae* having the identifying characteristics of a strain selected from the group consisting of Matlab I. Subsequent claims are drawn to a vaccine for protection against cholera comprising *V. cholerae* having the identifying characteristics of a strain selected from the group consisting of Matlab I.

Clemens et al. disclose a vaccine to be administered to humans comprising B subunit-killed whole cell vaccine, killed whole cell vaccine or a placebo. Each dose contained $1x10^{11}$ heat or formalin killed *V. cholerae* 01 whole cells, representing both the El Tor and classical biotypes and the Inaba and Ogawa serotypes. Additionally, 1 mg of cholera toxin B subunit was added to the vaccine (see page 760; materials and methods). Clemens et al. disclose that the vaccine is an oral vaccine (see title).

Since there are no specific "characteristics" recited, the *V. cholerae* of Clemens et al. anticipates the instant invention since they are the same bacterial species and therefore share a plethora of genotypic and phenotypic characteristics. Clemens et al. is necessarily effective against at least one organism selected from the group consisting of rotovirus and enterotoxigenic *E. coli*.

9. Claims 1-4, 8-13 and 15-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Sack et al. (The Journal of Infectious Diseases, 1991; 164: 407-11).

The rejected claims are drawn to an isolated strain of *V. cholerae* having the identifying characteristics of a strain selected from the group consisting of Matlab I. Subsequent claims are drawn to a vaccine for protection against cholera comprising *V. cholerae* having the identifying characteristics of a strain selected from the group consisting of Matlab I.

Sack et al. disclose a vaccine to be administered to humans comprising doses of killed oral agents for the prevention of cholera. The vaccines comprise killed whole cells representing both the El Tor and classical biotypes and the Inaba and Ogawa serotypes. A second vaccine included the same plus B subunit (see page 407; materials and methods).

Since there are no specific "characteristics" recited, the *V. cholerae* of Sack et al. anticipates the instant invention since they are the same bacterial species and therefore share a plethora of genotypic and phenotypic characteristics. Sack et al. is necessarily effective against at least one organism selected from the group consisting of rotovirus and enterotoxigenic *E. coli*.

10. Claims 1-4, 8 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Huq et al. (Applied and Environmental Microbiology, 1990; 56(8): 2370-73).

The rejected claims are drawn to an isolated strain of *V. cholerae* having the identifying characteristics of a strain selected from the group consisting of Matlab I.

Subsequent claims are drawn to a vaccine for protection against cholera comprising *V. cholerae* having the identifying characteristics of a strain selected from the group consisting of Matlab I.

Huq et al. disclose that *V. cholerae* were isolated from samples collected from established sampling sites (see page 2371; Results and Discussion).

Since there are no specific "characteristics" recited, the isolated *V. cholerae* strains of Huq et al. anticipates the instant invention since they are the same bacterial species and therefore shares a plethora of genotypic and phenotypic characteristics.

Claim limitations such as "a vaccine for protection against cholera" are being viewed as limitations of intended use. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 458.

Since the Office does not have the facilities for examining and comparing applicants' composition with the composition of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Conclusion

11. No claim is allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAKIA J. TONGUE whose telephone number is (571)272-2921. The examiner can normally be reached on Monday-Friday 8-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LJT
9/18/08

/Robert A. Zeman/

for Lakia J. Tongue, Examiner of Art Unit 1645